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10/676,176	10/01/2003	Fredrik Solhage	ANO 6277 US/3166	ANO 6277 US/3166 6797	
Michelle J. Bur	7590 06/13/200	7	EXAM	INER	
Akzo Nobel Inc Intellectual Property 7 Livingstone Avenue Dobbs Ferry, NY 10522			ISSAC, ROY P		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

ام.		Application No.	Applicant(s)		
		10/676,176	SOLHAGE ET AL.		
	Office Action Summary	Examiner	Art Unit		
		Roy P. Issac	1623		
Period fo	The MAILING DATE of this communication app or Reply	ears on the cover sheet with the o	orrespondence address		
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Status					
2a)⊠	Responsive to communication(s) filed on 3/28/3 This action is FINAL . 2b) This Since this application is in condition for allowan closed in accordance with the practice under E	action is non-final.			
Dispositi	on of Claims				
5)□ 6)⊠ 7)□	Claim(s) <u>1-28</u> is/are pending in the application. 4a) Of the above claim(s) is/are withdraw Claim(s) is/are allowed. Claim(s) <u>1-28</u> is/are rejected. Claim(s) is/are objected to. Claim(s) are subject to restriction and/or	vn from consideration.			
Applicati	on Papers				
10)	The specification is objected to by the Examiner The drawing(s) filed on is/are: a) access applicant may not request that any objection to the conference of the confere	epted or b) objected to by the lidrawing(s) be held in abeyance. See on is required if the drawing(s) is obj	e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d).		
Priority u	ınder 35 U.S.C. § 119				
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 					
Attachment	t(s)				
2) 🔲 Notice 3) 🔯 Inform	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date <u>3/28/2007</u> .	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	ite		

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DETAILED ACTION

This application claims priority under 35 U.S.C § 119(e) from the provisional application 60/415,184 filed 10/01/2002.

This Office Action is in response to Applicant's amendment/ remarks/ response filed 03/28//2007 wherein claims 1, 7, 11, 16, 21 and 25 have been amended is acknowledged. Claims 1-28 are currently pending.

Rejections Withdrawn

Applicant's arguments, see Page 7, Pargraph 5, filed 3/28/2007, with respect to rejection of claims 9 and 18 under 35 U.S.C first paragraph, have been fully considered and are persuasive. The rejection of claims 9 and 18 has been withdrawn. Applicants point out that claims 9 and 18 specify substitutents for aromatic and non-aromatic groups. Since the claim is directed to particular groups which are exemplified in the specification, the claims are deemed enabled.

Applicants' amendment reciting "cationic or anionic substituent having an aromatic group" removes the rejection of claims 1-4, 6, 8, 12, 15-17 and 21-23 under section 102(b) over Matsunaga et. al. The rejection of claims 1-4, 6, 8, 12, 15-17 and 19-23 has been withdrawn.

The rejection of claims 5, 7, 9-11, 13-14, 18 and 24-28 under section 103(a) over Matsunaga et. al in view of Persson et. al. has been withdrawn since applicants'

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amendment reciting "cationic or anionic substituent having an aromatic group" overcomes the obviousness rejection.

The following are modified rejections necessitated by Applicant's amendment filed 03/28/2007, wherein the limitations in pending claims 1, 7, 11, 16, 21 and 25 as amended now have been changed since claims 1 and 6 were amended. Claims 2-10 depend from amended claim 1, claims 12-18 depend from amended claim 11, claims 22-24 depend from amended claim 21, and claims 26-28 depend from amended claim 25. The limitations in the claims 1-18 and 21-28 have been changed and the breadth and scope of those claims have been changed. Therefore, rejections from the previous Office Action, filed 12/28/2006, have been modified and are listed below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8, 10-17, and 19-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for substituents $-CH_2$ -CH(OH)- CH_2 - $N^+((CH_3))_2)CH_2C_6H_5$ Cl-, and $-CH_2$ -CH(OH)- CH_2 - $N^+((CH_3))_3)Cl$ -, does not reasonably provide enablement for **any** aromatic or **any** non-aromatic substituents. The specification does not enable any person skilled in the art to which it pertains, or with

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which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The instant specification <u>fails</u> to provide information that would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention:

The instant application relates the cationization of polysaccharides with two quaternary amine substituents, one with an aromatic group and another without an aromatic group.

The relative skill of those in the art:

The relative skill of those in the art is high, with a typical practitioner having obtained a PhD, M.S. or equivalent advanced degree.

The breadth of the claims:

The instant claims are deemed very broad because they encompass any of the millions of substituents that can be considered either aromatic or non-aromatic. Claims where aromatic

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group is describes as "group containing 1 to 12 carbon atoms" encompass thousands of permutations of which only one is exemplified in the instant application.

The amount of direction or guidance presented and the presence or absence of working examples:

The instant application exemplifies polysaccharides cationised with two substitutents, the aromatic substituent –CH₂-CH(OH)-CH₂-N⁺((CH₃))₂)CH₂C₆H₅, and the non-aromatic substituent –CH₂-CH(OH)-CH₂-N⁺((CH₃)₃)Cl-. The specification further describes varying degrees of substitution of the two groups. However, no other substituent is exemplified. The term aromatic encompass a wide range of compounds with diverse properties, including varying reactivity, solubility and functionality. The operability of one particular aromatic substituent does not predict the operability of all other aromatic substituents. Similarly, the term non-aromatic group is also a description that encompasses a wide variety of groups with varying properties. Some examples of non-aromatic substituents include carbohydrates, lipids and long chain alkyl polymers, all of which have divergent chemical and physical properties. As such, one of skill in the art would not expect any substituents other than ones with strong structural similarity to the ones exemplified to function similarly.

"Aromatic implies various features, properties, or behaviors to chemists with different backgrounds." (Schleyer PV. Chemical Reviews, 2001, 1115-1117, Page 1117, Column 2, Paragraph 3; Of Record). The term aromatic despite its use in the literature is nonreductive. "They have no precise meaning and do not denote directly mreasurable quantities." (Page 1115, Column 1, Paragraph 3). They encompass large

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groups of compounds that often have dissimilar properties. For example, there are nonbenzenoid aromatics. Some of the compounds are negatively charged. (Page 1115, Column 2, paragraph 2). Some are heterocyclic while others are transition metal complexes. Different physical properties do not necessarily correlate with aromaticity criteria. (Page 1116, Column 2, Paragraph 3). Some of the heterocyclic complex are difficult to evaluate. (Page 1117, Column 1, Paragraph 1). In view of the complexity and breadth of "aromatic" compounds, the applicant have not enabled one of skill in the art to practice the invention in the full scope of the claims herein.

The lack of working examples is a critical and crucial factor to be considered, especially in cases involving an unpredicatable and undeveloped art. See MPEP § 2164.

The predictability or lack thereof in the art and the quantity of experimentation necessary:

Organic synthesis in particular is a very unpredictable art. Some of the synthesis efforts in organic chemistry take years to complete, often an exercise in trial and error. The generic claims in the instant application encompass thousands of compounds with wide varying functional groups. The additional groups claimed by the generic formula have well-established divergent function and properties.

Thus, the specification fails to provide <u>clear and convincing</u> evidence in <u>sufficient</u> support of the claimed compounds in their full scope described by the terms "aromatic group" and "non-aromatic" group.

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Genentech, 108 F.3d at 1366, sates that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the <u>Wands</u> factors as discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in <u>undue</u> <u>experimentation</u> to practice the invention commensurate in scope with the claims.

Response to Arguments

Applicant's arguments and additional references cited therein, filed 03/28/2007, with respect to the above rejections under 35 U.S.C 112, first paragraph have been fully considered but they are not persuasive

Applicants' argue that claims 5, 8-9, 14 and 17-18 are rejected improperly under 35 U.S.C 112, first paragraph since the previous office action acknowledges that the specification is enabling for the substituents identified in the working examples. However, claims 5, 8, 14 and 17 only specify one of the two substituents. As such, those claims are deemed properly rejected under 35 U.S.C first paragraph.

The applicants argue that the enablement rejections based on broadness of claims is improper. The breadth of the claims is one of the factors considered in rejections under 35 U.S.C 112, first paragraph. However, the examiner has included a

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Wands analysis that addressed factors beyond broadness of claims, including the amount of direction or guidance presented, the presence or absence of working examples, the predictability or lack thereof in the art and the quantity of experimentation necessary. (See pages 4-6 of the previous office action). The conclusion that a person of skill in the art would have to engage in undue experimentation to practice the invention commensurate in scope with the claims is reached in consideration of the several factors discussed in the previous office action, including the breadth of the claims. Applicants further argue that applicants descriptions such as "the substituents can be attached by a heteroatom", and the listing of a few preferred and more preferred substituents in the specification provides enablement for the full scope of the claimed encompassed by the terms "aromatic" and "non-aromatic". In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the preferred and more preferred aromatic substituents) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicants further assert that, "Although the application does not include working examples of a large number of aromatic and non-aromatic substituents, the specification does identify a significant number of preferred aromatic and non-aromatic substituents/ agents." The terms "aromatic" and "non-aromatic" together describes almost all imaginable substituents in organic chemistry. As pointed out in the previous

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office action, the instant application only exemplify polysaccharides cationised with two substitutents, the aromatic substituent $-CH_2-CH(OH)-CH_2-N^+((CH_3))_2)CH_2C_6H_5$ and the non-aromatic substituent –CH₂-CH(OH)-CH2-N[†]((CH₃)₃)Cl-. No working examples of any hetero-aromatic functionalities or lipids or carbohydrates provided. In applications directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims. (See In re Soll, 97 F.2d 623, 624, 38 USPQ 189, 191 (CCPA 1938)). In cases involving unpredictable factors, such as most chemical reactions and physiological activity, more may be required. (See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) (contrasting mechanical and electrical elements with chemical reactions and physiological activity). See also In re Wright, 999 F.2d 1557, 1562, 27 USPQ2d 1510. 1513 (Fed. Cir. 1993); In re Vaeck, 947 F.2d 488, 496, 20 USPQ2d 1438, 1445 (Fed. Cir. 1991)). This is because it is not obvious from the disclosure of one species, what other species will work. In view of the complexity and breadth of the terms "aromatic" and 'non-aromatic" compounds, representing almost all of the organic substituents, the applicants have not enabled one of skill in the art to practice the invention in the full scope of the claims herein.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8, 10-17 and 19-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitations "substituent having an aromatic group" and a "substituent having no aromatic group" renders the claim indefinite. The recited phrases do not convey a structural formula or chemical name to one of ordinary skill in the art. In the absence of a structural formula or chemical name, the claims reading on "substituent having an aromatic group" and "substituent having no aromatic group" wherein each variables are not distinctly claimed are indefinite as one of skill in the art would not be apprised of the metes and bounds of claimed invention.

No response/ arguments were filed over the above rejection under 35 U.S.C 112, second paragraph.

Rejection under 35 U.S.C. 112 second paragraph of claims 1-8, 10-17 and 19-28 is still deemed proper and is adhered to.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

⁽b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Matsunaga Y et.al. (JP 62149702, English Translation; PTO-1449, Included by the applicant).

Matsunaga et. al. discloses 3-chloro-2-hydroxypropyl trimethylammonium chloride (CMT) adduct of polysaccharide that further contains varying ranges of benzyl adduct. (Page 9, Table 1). Note that the 3-chloro-2-hydroxypropyl trimethylammonium chloride is the same non-aromatic substituent exemplified in the instant application. The polysaccharide from corn starch has a 2:1 ration of non-aromatic to aromatic substituent, while for tapioca, the ratio is 5:4, and for potato it is 3:4.7. (Table 1). Matsunaga discloses 6.5-10% substitution of CTA and 3-5% substitution of the aromatic group, benzyl chloride. The degree of cationization ranged from 3.9% to 6.0%. (Table 1). These ranges fall within the claimed ranges herein. Matsunaga further discloses a criteria for selecting substituents to prevent resolidification in paper manufacturing. (Page 2-3). The criteria includes the selection of a group with a high molecular weight and bulky structure, high boiling point. Matsunaga et. al. elects the benzyl as a group that meets this criteria in making benzyl substituted polysaccharides. (Page 4, lines 18-25). Benzyl chloride was added with CTA simultaneously to polysaccharide containing solution to get polysaccharides substituted with both groups. Even though Matsunaga does not report the charge density of the composition, it is expected to have the same charge density as the instant application because the compositions' substitution range falls within the instant application.

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Response to Arguments

Applicant's arguments filed 3/28/2007 have been fully considered but they are not persuasive. Applicants argue that Matsunaga et. al. do not disclose a cationized polysaccharide product that includes a cationic or anionic substituent having an aromatic group. However, claims 19 –20 are not amended to included the recitation "cationic or anionic substituent having an aromatic group". The rejection under section 102(b) is still deemed proper and is adhered to.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsunaga et. al. (JP 62149702, English Translation; PTO-1449, Included by the applicant), in view of Persson et. al. (WO 99/55964; PTO-1449, Included by the applicant).

Matsunaga et. al. discloses 3-chloro-2-hydroxypropyl trimethylammonium chloride (CMT) adduct of polysaccharide that further contains varying ranges of benzyl adduct. (Page 9, Table 1). Note that the 3-chloro-2-hydroxypropyl trimethylammonium chloride is the same non-aromatic substituent exemplified in the instant application.

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The polysaccharide from corn starch has a 2:1 ration of non-aromatic to aromatic substituent, while for tapioca, the ratio is 5:4, and for potato it is 3:4.7. (Table 1).

Matsunaga discloses 6.5-10% substitution of CTA and 3-5% substitution of the aromatic group, benzyl chloride. The degree of cationization ranged from 3.9% to 6.0%. (Table 1). These ranges fall within the claimed ranges herein. Matsunaga further discloses a criteria for selecting substituents to prevent resolidification in paper manufacturing.

(Page 2-3). The criteria includes the selection of a group with a high molecular weight and bulky structure, high boiling point. Matsunaga et. al. elects the benzyl as a group that meets this criteria in making benzyl substituted polysaccharides. (Page 4, lines 18-25). Benzyl chloride was added with CTA simultaneously to polysaccharide containing solution to get polysaccharides substituted with both groups. Even though Matsunaga does not report the charge density of the composition, it is expected to have the same charge density as the instant application because the compositions' substitution range falls within the instant application.

Matsunaga et. al. does not expressly disclose a cationized or anionized aromatic substituent or the use of the particular aromatic quaternary amine substituent of the general structure I of the instant application. Matsunaga et. al. does not disclose substitutents wherein R1, R2 and R3 together with N form an aromatic group containing 5-12 carbon atoms.

Persson et. al. discloses cationised polysaccaharides with quaternary ammonium substituents. The cationized polysaccharides have the following structure, as disclosed

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in the instant application including the particular substituents exemplified in the instant application. (Page 4, lines 3-25).

$$R_1$$
 (I)
 X^*
 $P - (-A - N^* - R_2)_n$
 R_3

Persson et. al. discloses 2-hydroxypropyl dimethyl benzyl ammonium chloride (a cationic substituent having an aromatic group) as one of the hydrophobic substituents for polysaccharides. (Example 1, Page 11, lines 20-30). Persson et. al. discloses substituents where R1, R2 and R3 together with N form an aromatic group containing 5-12 carbon atoms. Presson et. al. discloses two polysaccharide polymers each individually has the particular substituents of the instant application. (Page 11, Example 1, compounds P1 and Ref 1). Persson et. al. further discloses epichlorohydrin as a suitable modifying agent.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to synthesize a polysaccharide with a first substituent comprising – CH2-CH(OH)-CH2-N⁺((CH3)2)CH2C6H5 Cl- and the second substituent -CH2-CH(OH)-CH2-N⁺((CH3)3)Cl-, because Matsunaga et. al. discloses a polysaccharide with two types of substituents, one aromatic and one non-aromatic as claimed herein, and Persson et. al. discloses the particular aromatic substituent –CH2-CH(OH)-CH2-N⁺((CH3)2)CH2C6H5 Cl- for polysaccharides. Note that, independent claims 21 and 25

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are in the product-by-process format. These two claims appear to give rise to the same products claimed in claims 1-20.

One of ordinary skill in the art would have been motivated to use the particular substituents of the instant application because Matsunaga et. al. discloses polysaccharides with two types of substituents, one particular substituent (non-aromatic) identical to the instant application, and the other structurally similar to the one claimed herein, well known for use as substituent in polysaccharide paper production by Persson et. al. If the claimed invention and the structurally similar prior art species share any useful property, that will generally be sufficient to motivate an artisan of ordinary skill to make the claimed species. It is a reasonable expectation that similar species usually have similar properties. See Dillon, 919 F.2d at 693, 696, 16 USPQ2d at 1901, 1904. See also, Deuel, 51 F.3d at 1558, 34 USPQ2d at 1214. In fact, similar properties may formally be presumed when compounds are very close in structure.

Dillon 919 F.2d at 693, 696, 16 USPQ2d at 1901, 1904, as noted in MPEP 2144.

One of ordinary skill in the art would have reasonably expected that the substitution of –CH2-CH(OH)-CH2-N⁺((CH3)2)CH2C6H5 CI- instead of benzyl chloride would have resulted in polysaccharide with beneficial properties in paper production.

As such, the invention is prima facie obvious over the combined teachings of the prior art.

Response to Arguments

Applicant's arguments filed 3/28/2007 have been fully considered but they are not persuasive. Applicants argue that Persson et. al discloses aromatic substitution by

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ammonium chloride group which is a cationic substituent having an aromatic group. Applicants further argue that the present invention provides unexpected results. However, the comparisons of Table 1 only compares the product of the instant application with mono substituted polysaccharides. Matsunaga's disclosed polysaccharide with one aromatic substituent and one non-aromatic substitutent is considered the closest prior art. It is applicant's burden to demonstrate unexpected results over the closest prior art. See MPEP 716.02, also 716.02 (a)-(g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. Ex Parte Gelles, 22 USPQ2d 1318, 1319 (Bd. Pat. App & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing". In re Lohr, 137 USPQ 548 (CCPA 1963), In re Linder, 173 USPQ 356 (CCPA 1972).

As such, the rejection under section 103(a) is still deemed proper and is adhered to.

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No Claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy P. Issac whose telephone number is 571-272-2674. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Roy P. Issac Patent Examiner Art Unit 1623 S. Anna Jiang, Ph.D.

Supervisory Patent Examiner

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